



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 31, 2018

Kim Davis
Consultant/Agent
c/o RegWest Company, LLC
8203 West 20th St., Suite
Greeley, CO 80634-4696

Subject: Notification per PRN 98-10 – Revising the label to update the company address and add additional brand names
Product Name: Aquastat-HU
EPA Registration Number: 79630-1
Application Date: December 26, 2017
Decision Number: 537368

Dear Ms. Davis:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

The alternate brand names have been added to the product record:

- Protec ® Advanced
- Protec ® Germ Free Cartridge
- Protec ® Germ Killing Humidifier ball [capsule][Drop in]
- Protec ® Germ Killing Sphere [Ball] [Capsule]
- Protec ® Germ Killing Sphere [Ball] [Capsule] for Humidifier
- Protec ® Humidifier Germ Killing Ball [sphere]
- Protec ® Plus

- Protec ® up to 99.9% Germ Free Cartridge

If you have any questions, you may contact Zebora Johnson at (703) 308-7080 or via email at johnson.zebora@epa.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Zeno Bain".

Zeno Bain,
Product Manager, 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted label

AQUASTAT®-HU

{ABNs: AquaStat®-HUC for CPAP;
Protac® Advanced;
Protac® Antimicrobial Cartridge;
Protac® Germ Free Cartridge;
Protac® Germ Killing Humidifier Ball [Capsule] [Drop In];
Protac® Germ Killing Sphere [Ball] [Capsule];
Protac® Germ Killing Sphere [Ball] [Capsule] for Humidifier;
Protac® Humidifier Cleaning Ball;
Protac® Humidifier Cleaning Fish;
Protac® Humidifier Germ Killing Ball [Sphere];
Protac® Plus; and
Protac® up to 99.9% Germ Free Cartridge}

NOTIFICATION

79630-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

1/31/2018

{Select marketing claims from the *Marketing Claims* section below}
Microbistatic [Antimicrobial] Treatment for Residential Humidifier Units

Active Ingredient:

Silver (metallic)	1.4%
Other Ingredients	<u>98.6%</u>
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

Do not allow children to play with the [AquaStat-HU cartridge] [descriptor] [Brand Name]

EPA Reg. No. 79630-1 EPA Est. No. 79630-GA-001

Lot/Batch Number: _____

Net Weight {one each cartridge [descriptor]}: _____ oz

{For two cartridges in package:}

Net Contents: 2 cartridges [descriptors], Total Net Weight: _____ oz
{one or two cartridges per package}

Manufactured for [by]
K2 Concepts, Inc.
114 N. Prince Street, 3rd Floor
Lancaster, PA 17603
805 Peachtree Street NE, Suite 614
Atlanta, GA 30308

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Remove outer package before placing cartridge [descriptor] into humidifier. Do not open or attempt to empty the cartridge [descriptor]. Retain this label for reference.

{Option 1 Directions – paragraph numbering is optional}

For use in the following sizes of residential humidifiers: Small portable humidifier units, Console humidifier units, Central humidifier units. For use in the following types of residential humidifiers: Ultrasonic, Cool mist (impeller), Evaporative, Steam vaporizer.

1. For every 2 gallons of water contained in the humidifier tank, use 1 AQUASTAT-HU cartridge **[[descriptor]]**.
2. For best results, before using for the first time, it is recommended that you clean your humidifier according to the humidifier manufacturer's instructions to remove any buildup that may have accumulated.
3. After humidifier has been cleaned, drop ~~one (1)~~ AQUASTAT-HU cartridge **[[descriptor]]** per 2 gallons of water capacity into the humidifier water reservoir and fill tank with fresh water. **For humidifiers with 2 tanks use 1 AQUASTAT-HU cartridge **[[descriptor]]** per tank.**
4. Operate humidifier according to the manufacturer's directions and replace AQUASTAT-HU cartridge **[[descriptor]]** every 30 days. For deep-well reservoir tanks, shut off water and drain tank in order to retrieve the AQUASTAT-HU cartridge **[[descriptor]]**.

{Option 2 Directions: Alternate Wording for 0.035 oz (1 gram ~~(0.035-oz)~~) cartridges for very small units (<17 fl oz (500 ml) capacity) – paragraph numbering is optional}

For Units with Capacity of ~~<17 fl oz (<500 ml)~~:

1. For every ~~17 fl oz (500 ml) (17 fl-oz)~~ of water contained in the humidifier tank, use 1 AQUASTAT-HU cartridge **[[descriptor]]**.
2. For best results, before using for the first time, it is recommended that you clean your humidifier according to the humidifier manufacturer's instructions to remove any buildup that may have accumulated.
3. After humidifier has been cleaned, drop ~~one (1)~~ AQUASTAT-HU cartridge **[[descriptor]]** per ~~17 fl oz (500 ml) (17 fl-oz)~~ of water capacity into the humidifier water reservoir and fill tank with fresh water.
4. Operate humidifier according to the manufacturer's directions and replace AQUASTAT-HU cartridge **[[descriptor]]** every 30 days. **For deep-well reservoir tanks, shut off water and drain tank in order to retrieve the AQUASTAT-HU cartridge.**

{Option 3 Directions – paragraph numbering is optional}

For use with household humidifiers:

1. Drop ~~one (1)~~ AQUASTAT-HU cartridge **[[descriptor]]** **[[brand name]]** into the humidifier tank. Use one cartridge **[[descriptor]]** **ball** for up to ~~two (2)~~ gallons of water.
2. Fill tank with fresh water.
3. Operate humidifier according to the manufacturer's directions and replace the **[[descriptor]]** **[[brand name]]** after 30 days of use.

STORAGE AND DISPOSAL

Storage: Do not store in areas accessible to children. Keep product dry during storage.

Disposal: ~~Nonrefillable cartridge **[[descriptor]]**; do not reuse or refill this empty cartridge **[[descriptor]]**. Securely wrap cartridge in several layers of newspaper and **if empty:** Discard in trash or offer for recycling, if available. **if partly filled:** Call you local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.~~

Container Disposal: ~~Securely wrap outer carton in several layers of newspaper and discard in trash or offer for recycling, if available.~~

Notice: Customer is responsible for ensuring compliance with applicable laws and regulations. Any use of this product for purposes other than what is intended is strictly prohibited. Results may vary according to water quality.

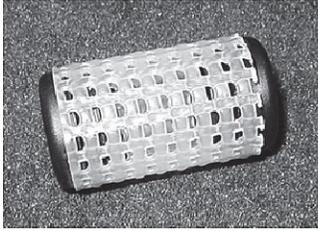
{Optional} *{Description of Cartridge (no more than one of these will appear on the printed label, but either/neither may be used)}*

{Type 1: Cylinder}

Cylinder composed of 100% polypropylene, with caps of 100% LDPE.

Dimensions: 2 inches (L) x 1.25 **inches** **∅** (D)

Dimensions for smaller size units (\leq 17 fl. oz (500 ml) capacity): 0.5 inch (12 mm) (L) x 0.3 inch (8 mm) (D)



{Type 2: Sphere}

Sphere composed of 100% polystyrene. Dimensions: 1 inch (30 mm) (D)



{Optional product description language:}

Why use an {AQUASTAT-HU} { Protec } {brand name} cartridge {descriptor}?

Humidifier tanks hold water which is an ideal breeding ground for microorganisms. This can cause odor and buildup, and may require more frequent cleaning. The {AQUASTAT-HU} { Protec } {brand name} cartridge {descriptor}: *{followed by one or more optional marketing claims listed below on-label}*

{Optional Marketing Statements}

Contains no {abrasives} [or {harsh acids}]

[Contains] No {harsh} [harmful] [lingering] {cleaning} chemicals

Continually inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae on humidifier surfaces

Continuously cleans and protects humidifiers [vaporizers] against {bacteria} [mold] [algae]

Continuously works to control [prevent] [inhibit] growth of {bacteria} [mold] [slime] [buildup of slime] in the water and humidifier [vaporizer] surfaces

{Controls} [Continually inhibits] [prevents] growth [and buildup] of bacteria, mold and algae in the water tank

{Controls} [Continually inhibits] [prevents] growth of {bacteria} [mold] and [algae] [microorganisms] in the mist of cool-mist humidifiers [vaporizers] during the life of the cartridge {descriptor}

Extends the life of the humidifier [vaporizer] by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]

Extends the life of the humidifier [vaporizer] filter/components [wick] by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]

{Gentle} [mild] cleaning action for your humidifier

Improves humidifier [vaporizer] performance by eliminating [preventing] [controlling] slime-causing microorganisms [bacteria] [mold] [algae]

Inhibits the growth of up to 99% of odor-causing bacteria, unsightly mold and algae keeping your humidifier cleaner, longer

Just as {gentle} [mild] as {soap} {and} {water} on your humidifier

Just as {gentle} [mild] as {soap} {and} {water} to humidifier surfaces and components

Just drop in humidifier tank[!] {already approved elsewhere in conjunction with graphics}

Keeps working [cleaning] for 30 days

Keeps your humidifier cleaner, longer

Kills bacteria [microorganisms] that cause unpleasant odors

Kills up to 99% of odor-causing bacteria

Leaves no {harsh} [harmful] [lingering] [corrosive] residues

Made in the {USA} [{country of origin}] [Product of {country of origin}]

Microbiostatic [Antimicrobial] Treatment for Residential Humidifier Units

Non-~~corrosive~~ ~~[corroding]~~
[Offers] Continuous protection against slimy build-up in ~~[humidifier]~~ ~~[vaporizer]~~
Prevents the growth of bacteria, mold and algae in the water and on the inside of the humidifier ~~[vaporizer]~~ tank
Prevents the buildup of slime on the inside of the humidifier ~~[vaporizer]~~ tank
Provides fresh mist
Provides both continuous cleaning and protection against odor ~~[slime]~~ causing ~~[microorganisms]~~ ~~[bacteria]~~ ~~[mold]~~ ~~[fungi]~~ ~~[algae]~~
Reduces up to 99% of odor-causing bacteria, unsightly mold and algae growth versus untreated humidifier surfaces,
Simply drop in tank for fresh, clean mist
Uses the same antimicrobial that has been used for years in drinking water filters to prevent objectionable odors, tastes and colors
~~[Will not harm]~~ ~~[Non-harmful to]~~ ~~[metal]~~ ~~[plastic]~~ ~~[humidifier]~~ components
Works in ~~[virtually]~~ all ~~[residential]~~ ~~[humidifiers]~~ ~~[vaporizers]~~
Your humidifier ~~[vaporizer]~~ stays cleaner, longer
You can actually see the difference!
Silver technology keeps your humidifier surfaces clean
{End of Marketing Statements}

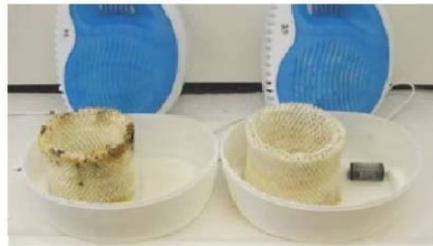
{Optional product stewardship language}
Choking hazard
This is not a toy!!
Questions or comments? {phone number} [email] ~~[website]~~
{End of Optional product stewardship language}

{Optional trademark/patent statements}
US Patent No. 7,422,759 [and others pending]
AquaStat® is a registered trademark of K2 Concepts Inc., [Atlanta GA]
Protec® is a registered trademark of Helen of Troy Limited
{End of Optional trademark/patent statements}

{Optional graphics}



Photograph of actual results using AQUASTAT-HU cartridge ~~[descriptor]~~



Typical humidifier without using
AQUASTAT-HU cartridge
~~[descriptor]~~

Typical humidifier using
AQUASTAT-HU cartridge
~~[descriptor]~~

{Text that may accompany the above graphic:}
{Above or below graphic:} Photograph of actual results using [AQUASTAT-HU] [Protec] [brand name] [cartridge]
{On the left side/pointing to the left side:} Typical humidifier without using [AQUASTAT-HU] [Protec] [brand name] [cartridge]
{On the right side/pointing to the right side:} Typical humidifier using [AQUASTAT-HU] [Protec] [brand name] [cartridge]



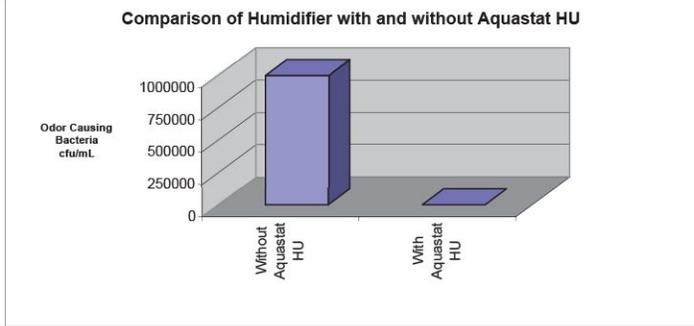
{May will be placed adjacent to the current claim: Reduces up to 99% of odor causing bacteria, unsightly mold and algae growth versus untreated humidified surfaces.}

{May will be placed adjacent to the Directions for Use section or adjacent to the claim: Just drop in humidifier tank or elsewhere on the label.}

{May will be placed adjacent to the Directions for Use section or elsewhere on label; may be adjacent to the claim: Just drop in humidifier tank.}

{Optional Marketing Graphic}

Virtually no odor and slime-causing bacteria found in humidifier using Aquastat HU



{Aquastat Logo}



{End of Optional graphics}

[] = denotes alternate/optional language

{ } = denotes language that does not appear on the market labeling